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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,249	05/03/2001	David F. Woodward	D2910	6273

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EXAMINER

FAY, ZOHREH A

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 12/17/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/848,249

Applicant(s)

Woodward et al.

Examiner

Zohreh Fay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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Claims 1-23 are presented for examination.

The Information Disclosure Statement filed on May 3, 2001 has been received and entered.

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-23 are rejected under 35 U.S.C. 103 as being unpatentable over Cupps et al.

(U.S. 5,916,900).

Cupps et al. Teach the use of an alpha adrenergic agonist in a pharmaceutical formulation for the treatment of diseases associated with alpha-2 adrenoreceptor. See the abstract. The above reference on column 14, lines 59-66 teaches the addition of different oils to alpha-2 agonists as old. The above reference differs from the claimed invention in the presence of specific alpha-2 agonists and specific fatty acids in the dependent claims. The above reference also differs from the claimed invention in the presence of limitation such as forming a complex between alpha-2 adrenergic and fatty acids. One skilled in the art would have been motivated to employ the teachings of the above reference, since it relates to the use of alpha-2 adrenoreceptor agonists in combination with fatty acids in a pharmaceutical formulation. The above reference makes clear that addition of fatty acids as carriers to the pharmaceutical compositions containing alpha-2 adrenoreceptor agonist is old and well known. The substitution of one alpha-2 adrenergic agonist for another is considered to be within the skill of the art in the absence of evidence to the

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contrary. Applicant uses the limitation of forming a complex between the alpha-2 adrenoreceptor agonists and the fatty acids. Such limitation does not create a patentably distinct composition, considering that mixture of different compounds always creates some kind of complex. In the absence of any critical features to the claimed complex, such limitation does not create a patentably distinct composition. The addition of a use such as increasing the permeability also does not create a patentably distinct composition since claims are composition claims and not method of use claims. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 1-23 are properly rejected under 35 U.S.C. 103.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Fay whose telephone number is (703) 308-4604.

ZOHREH FAY  
PRIMARY EXAMINER  
GROUP 1200

